

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GEDULIN, B., et al.

Appln. No.: 10/671,304

Filed: Sept. 24, 2003

For: Treatment of Pancreatitis
With Amylin

Art Unit: 1655

Examiner: WINSTON, Randall O.

Atty. Docket: 0101US-UTL

Confirm. No.: 8486

APPEAL BRIEF

Commissioner for Patents
Mail Stop Appeal Brief
P.O. Box 1450
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Sir:

In response to the Office Action mailed January 31, 2011 and subsequent to the Notice of Appeal filed June 28, 2011, Applicant submits the following Appeal Brief.

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Real Party in Interest

The real party in interest in the case is Amylin Pharmaceuticals, Inc., the assignee of record.

Related Appeals and Interferences

There are no other appeals, interferences, or judicial proceedings related to this case.

Status of the Amendments

No amendments were submitted after final rejection.

Summary of Claimed Subject Matter

The present invention involves a method of treating pancreatitis in a mammalian subject afflicted with pancreatitis (p. 4, lines 4-5 and 9). The method involves administering to the subject an effective amount of an amylin or an amylin analog (p. 4, lines 7-9; p. 14, lines 1-2). The amylin analog has amylin agonist activity (p. 6, lines 12-19). The method of treatment involves reducing or inhibiting the level of inflammation, enzymatic activity or enzymatic secretion in pancreatic cells (p. 5, lines 13-17).

Grounds of Rejection to be Reviewed

Whether claims 1, 6, 9, 27, 29, 31 and 33-40 are unpatentable under 35 U.S.C. 103(a) as being obvious over Young et al. (US 5,677,279) in view of Iovanna et al. (US 5,436,169), Valter (Derwent Acc 1979-G6671B and/or SU 628925A, see abstract), Sachs et al. (US 20010018049), Jorgensen et al. (US 4,370,317) and Haddad et al. ("The Use of a Low Fat Diet in the Treatment of Acute Pancreatitis" *Am J Gastroent* (Sept. 2000), Vol. 95, No. 9, pp. 2479).

Argument

Rejection of claims 1, 6, 9, 27, 29, 31 and 33-40 Under 35 U.S.C. 103(a) as being obvious over Young in view of Iovanna, Valter, Sachs, Jorgensen and Haddad

Claims 1, 6, 9, 27, 29, 31 and 33-40 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Young (USP 5,677,279) in view of Iovanna (USP 5,436,169), Valter (Derwent Acc 1979-G6671B and/or SU 628925A, abstract), Sachs et al. (US 20010018049), Jorgensen (USP 4,370,317), and Haddad ("The Use of a Low Fat Diet in the Treatment of Acute Pancreatitis," *American Journal of Gastroenterology*, (Sept. 2000), Vol. 95, No. 9, pp. 2479.

Young discloses that amylin and pro-h-amylin can be used for analgesia in mammals (Col. 5, lines 55-61). Contrary to what is asserted in the Office Action, Young does not disclose treatment of any "inflammation" disorders (Office Action mailed 1/31/11, p. 3, lines 1, 4, 7, p. 4, line 6). Iovanna discloses that acute abdominal pain is one indicia of diagnosis of acute pancreatitis. Nevertheless, the present invention is not directed towards treating pain. Valter discloses that acute pancreatitis is a very painful inflammation condition. Sachs discloses that acute pancreatitis and chronic pancreatitis are very painful inflammation conditions.

The rejection alleges that it would have been obvious to administer pro-h-amylin and an analgesic to treat pancreatitis because Young discloses that pro-h-amylin and an analgesic treats "painful inflammation disorders" and Iovanna and/or Valter and/or Sachs teach that acute pancreatitis and/or chronic pancreatitis are painful inflammation disorders, and thus the amylin analog would "intrinsically treat the broadly genus claimed pancreatitis disorder" (final Office Action mailed 1/31/11, p. 4, lines 13-15).

First, Applicant points out that Young does not disclose amylin for treatment of "painful inflammation disorders." Young never mentions inflammation. Young discloses that amylin can be used for analgesia in mammals. Second, by alleging that pancreatitis would be "intrinsically" treated, the rationale of the rejection is clearly based on the concept of inherency.

The rejection alleges that by administering amylin as an analgesic to a patient suffering from pain, one is inherently treating pancreatitis (Office Action mailed 8/25/10, p. 4; Office action mailed 1/31/11, p. 4). The rejection uses the word “intrinsically” but this is merely a substitute for “inherently” and Applicants submit that the mere substitution of “intrinsic” for “inherent” does not change the rationale of the rejection from one of anticipatory inherency. Such a concept of inherency is necessarily contained in the rejection because Young provides no disclosure or suggestion to utilize amylin for the treatment of pancreatitis, or that its administration causes a lowering of pancreatic enzymes.

But inherency is a concept applicable only in the context of anticipation, not obviousness. Claims can only be anticipated by inherency, and there is no legal theory of obviousness by inherency, therefore the rejection has no legal basis. The Federal Circuit has made clear that “a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection.” *In re Rijckaert*, 9 F.3d 1531; 28 USPQ2d 1955 (Fed. Cir. 1993). Thus, without the requisite disclosures, suggestions or rational underpinning required to support an obviousness rejection, no prima facie case of obviousness has been made.

The proper analysis under 35 U.S.C. 103(a) for obviousness is to apply the *Graham* factors. *Graham v. John Deere, Co.*, 383 U.S. 1, 148 USPQ 459 (1966). The factual inquiries enunciated by the Supreme Court are a) ascertaining the differences between the claimed invention and the prior art; and b) ascertaining the differences between the claimed invention and the prior art; and c) resolving the level of ordinary skill in the pertinent art. *Id.*

The Examiner must thus step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the “differences,” conduct the search and evaluate the “subject matter as a whole” of the invention. Impermissible hindsight must be

avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. MPEP 2142.

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reasons why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398; 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). MPEP 2142. But here, no articulated reasoning with some rational underpinning to support the legal conclusion of obviousness has been provided in the rejection.

The rejection also includes the citation of Jorgensen and Haddad. But these references provide no information that cures the deficiencies explained above, thus even with these references combined no prima facie case of obviousness has been made.

The claims are not rendered obvious by the cited references for yet another reason, which is that administration of amylin to a patient suffering from pancreatitis provides the unexpected benefit of simultaneously reducing pancreatic enzyme levels associated with the disease (specification, paragraph 73). This benefit is not disclosed or suggested by any of the cited references or combination thereof.

Additionally, the present claim recites that the method is for treating pancreatitis in a mammalian subject afflicted with pancreatitis. Thus, the claim requires that the methods be performed on a subject actually afflicted with pancreatitis. The Federal Circuit has held that where a claim was drawn to treating or preventing a specific disease and where the claim required that the active ingredient be administered "to a human in need thereof," that the need must be recognized and appreciated for the claim to be infringed. *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 68 USPQ2d 1154 (Fed. Cir. 2003). In the present case the claims are drawn to treating pancreatitis in a subject that is afflicted with pancreatitis. And in like manner these

claims require that the need be recognized and appreciated and that the subject be afflicted with pancreatitis, and that the amylin or amylin agonist be administered for the purpose of treating the pancreatitis. *Jansen* (“The preamble is ... a statement of the intentional purpose for which the method must be performed”). Since none of the cited references, nor any combination thereof, teach or suggest such a treatment, the claims are not rendered obvious by the cited references.

For all of these reasons, the claims are not obvious over the cited combination. Therefore, no prima facie case of obviousness has been made and the rejection should not stand.

It is further noted that even using a legally incorrect inherency rationale, the rejection would still fail because Federal Circuit decisions have emphasized that an anticipatory inherent feature or result must be consistent, necessary, and inevitable, not merely possible or probable. (emphasis added) *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1373; 62 USPQ2d 1865 (Fed. Cir. 2002) (“anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation”) (emphasis added); *Akamai Technologies, Inc. v. Cable & Wireless Internet Svcs, Inc.*, 344 F.3d 1186; 68 USPQ2d 1186 (Fed. Cir. 2003) (“in order for a claim limitation to be inherent in the prior art it must necessarily be present in the prior art, not merely probably or possibly present.”). Thus, inherency “may not be established by probabilities or possibilities.” *In re Robertson*, 160 F.3d 743; 49 USPQ2d 1949 (Fed. Cir. 1999). And “the mere fact that a certain thing may result from a given set of circumstances is insufficient to prove anticipation...” *Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048; 32 USPQ2d 1017 (Fed. Cir. 1994). Rather, it is necessary to prove the feature is “necessarily present in the disclosure, and that it would be so recognized by persons of ordinary skill.” (*Id.*, emphasis added).

In the present case the claimed invention is not “necessarily” practiced while treating pain because pancreatitis does not always accompany pain. The treatment of pancreatitis does not invariably happen in the referenced treatment of pain, and thus even using an inappropriately applied inherency analysis, the rejection still fails. Since pancreatitis does not invariably accompany pain, the treatment of pain with amylin does not inherently involve the treatment of pancreatitis with amylin.

For at least these reasons, independent claim 1 and claims dependent therefrom are believed to be patentable over the prior art of record, and reversal of this rejection is respectfully requested.

Claims Appendix

1. A method of treating pancreatitis in a mammalian subject afflicted with pancreatitis comprising

administering to said subject an effective amount of an amylin or an amylin analog, wherein the amylin analog has amylin agonist activity,

wherein the level of inflammation, enzymatic activity or enzymatic secretion in pancreatic cells of said subject is reduced or inhibited.

6. The method of claim 1 wherein said subject is a human.

9. The method of claim 1 wherein said amylin analog is ^{25,28,29}Pro-h-amylin.

27. The method of claim 1 wherein 0.1 µg to 1 mg of said amylin or said amylin analog is administered to said mammalian subject in a single, divided, or continuous dose.

29. The method of claim 1 wherein about 2 µg to about 8 mg per day of said amylin or said amylin analog is administered to said mammalian subject.

31. The method of claim 1 wherein the amylin or amylin analog is amylin.

34. The method of claim 1 wherein the pancreatitis is acute pancreatitis.

35. The method of claim 1 wherein the pancreatitis is chronic pancreatitis.

36. The method of claim 34 further comprising administering to the subject an agent or regimen used to treat acute pancreatitis.

37. The method of claim 36 wherein the agent is clinically used to treat pancreatitis.

38. The method of claim 36 wherein the agent is a pancreatic enzyme.

39. The method of claim 36 wherein the regime includes a low-fat diet.

40. The method of claim 36 further comprising administering to said subject an analgesic.

Evidence Appendix

None.

Related Proceedings Appendix

None

Closing

In view of the above the Applicant respectfully requests that the rejections be reversed and that the claims be passed to allowance.

Respectfully submitted

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Date

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